

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

AMERITOX, LTD., and
MARSHFIELD CLINIC, INC.,

Plaintiffs,

v.

MILLENNIUM HEALTH, LLC,

Defendant.

OPINION & ORDER

13-cv-832-wmc

In advance of the final pretrial conference set for April 7, 2015 at 1:30 p.m., the court issues the following opinion and order on the parties' pending motions in limine, as well as a recently-filed joint request for expedited guidance on "order of proofs" at trial (dkt. #374). As explained below, the court will bifurcate trial with the first phase solely consisting of Millennium's invalidity challenges; assuming the jury finds the '680 patent valid, the second phase will concern damages and, if appropriate, willful infringement. As for the numerous motions in limine, for ease, the court has organized the motions by primary area of concern, *i.e.*, validity, damages and willful infringement.

OPINION

I. Joint Request for Order of Proofs at Trial

In a joint submission, the parties set forth their respective positions on the order of proofs. Ameritox seeks to depart from this court's usual practice by presenting its willful infringement claim first, followed by Millennium's invalidity challenges, with both going to the jury in the first phase of the trial. The second phase of the trial, therefore, would solely consist of damages. Millennium, on the other hand, wishes to proceed with

invalidity in the first phase of trial, saving both damages and willful infringement for the second phase.

Since plaintiffs offer no compelling reason to depart from usual practice, this is not a close question. At the start of the trial, the jury will be informed that the court has already determined that Millennium infringes the '680 patent. The only issue, therefore, remaining as to liability is Millennium's invalidity challenges. Because a jury's finding of willful infringement is only material in determining the appropriate damages award and has no impact on any liability issue, the court finds generally that it is best-suited for the second phase of a bifurcated trial. The argument that "[p]laintiffs traditionally present first and this case should be no exception because Plaintiffs bear the burden of proof on willful infringement" (Joint Submission (dkt. #374) 1) is silly. Plaintiffs also have the burden on proving damages, but that does not serve as a basis for having the jury consider damages before hearing Millennium's invalidity challenges.

Moreover, the jury need not reach willful infringement if either (1) the court determines that plaintiffs have failed to prove by clear and convincing evidence that Millennium "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent," *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*) (*see infra* Section IV.A.); or (2) the jury finds in favor of Millennium on its challenges to the validity of the '680 patent. Judicial economy, therefore, strongly favors trying willful infringement as part of the second phase of the trial.

The only credible concern plaintiffs raise is that some of the evidence they wish to submit in response to Millennium's obviousness challenge -- namely, evidence of copying

-- is also relevant to its claim of willful infringement. *See SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1377 (Fed. Cir. 2013) (considering evidence of copying by competitors as objective evidence of non-obviousness). To clarify, if the evidence is relevant to obviousness, nothing about this order precludes plaintiffs from introducing that evidence in the first phase of the trial. The court, however, will not allow plaintiffs to present the same evidence twice. Rather, plaintiffs can simply reference testimony and evidence already received during the first phase of trial in its opening and closing arguments for the second phase. This approach also addresses at least some of Ameritox's concerns about convenience for Millennium's witnesses.

II. Plaintiffs' Defense to Millennium's Invalidity Claims

A. First Motion in Limine to Exclude Evidence Concerning Certain Defenses (dkt. #277)

Under Federal Rules of Evidence 402 and 403, plaintiffs seek to exclude evidence concerning any alleged waiver, laches, license, release, inequitable conduct, lack of enablement, indefiniteness, lack of utility, lack of patentable subject matter, or non-infringement. (Pls.' First Mot. (dkt. # 277) 1.) Much of this motion in limine is made moot by Millennium's response. (Def.'s Opp'n (dkt. #329) 1-2.) Specifically, Millennium has determined "not to present its defenses of inequitable conduct, waiver, laches, license and release, as well as defenses predicated on Millennium's proposed claim construction, including indefiniteness, enablement and utility, following assessment of the Court's recent summary judgment orders and its claim construction determinations."

(*Id.* at 1.) This leaves the issue of whether the motion should be granted to exclude evidence supporting Millennium's patent eligibility defense under 35 U.S.C. § 101.

The court will deny this aspect of the motion for two reasons. First, the court simply denied Millennium's summary judgment motion on patentable subject matter; it did not grant summary judgment of no invalidity. (2/19/15 Op. & Order (dkt. #215).) Second, a motion in limine is not the proper vehicle for excluding Millennium's § 101 challenge to the '680 patent. Plaintiffs made no effort to file a motion for summary judgment on this issue and its *de facto* use of Rules 402 and 403 will go unheeded. Accordingly, plaintiffs' motion as applied to 35 U.S.C. § 101 is denied.

B. Second Motion in Limine to Exclude Arguments Contrary to the Court's Claim Construction (dkt. #279)

Plaintiffs seek to exclude Millennium making arguments contrary to the court's claim construction opinion. (2/19/15 Op. & Order (dkt. #215).) Millennium opposes the motion, arguing that plaintiffs have overreached, particularly with respect to willful infringement.

The parties' concerns are largely accommodated by the court's use of a bifurcated trial. While Millennium will be precluded from interjecting dose-prediction limitations into the asserted claims at the liability phase of the trial, Millennium will be afforded the opportunity to rebut plaintiffs' willful infringement claim with such evidence, as well as legal argument. In particular, Millennium may present any additional evidence and argument on this issue to the court while the jury is deliberating on invalidity and damages. *See, e.g., Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1374 (Fed. Cir.

2008) (affirming finding of no willful infringement despite rejecting defendant's claim construction where that construction was reasonable "in light of the specification and prosecution history.").

With the exception of the willfulness phase, Millennium will also be precluded from (1) cross-examining the inventor Dr. Larson (or any other witness) in any way that suggests the claimed invention is limited to dose prediction; (2) arguing or suggesting that Rx Guardian CD, which practices the asserted patent, is intended to or does predict dose; and (3) offering any evidence or argument suggesting that it does not infringe the asserted claims.

C. Fifth Motion in Limine to Exclude Preston as Prior Art (dkt. #282)

Plaintiffs seek an order excluding the introduction of the Preston Article.¹ While the motion reads like an unlikely motion for summary judgment, there are some aspects that go to evidentiary issues worthy of consideration. As an initial matter, "[w]hen considering whether a given reference qualifies as a prior art 'printed publication,' the key inquiry is whether the reference was made 'sufficiently accessible to the public interested in the art' before the critical date." *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012) (citation omitted), *cert. denied*, 133 S. Ct. 2804 (2013).

Plaintiffs contend that Preston should be excluded for two reasons. First, plaintiffs contest a sworn affidavit by a third party, Todd Fenton. (Todd Fenton Affidavit

¹ Preston, K. *et al.*, *Methadone and Metabolite Urine Concentrations in Patients Maintained on Methadone*, *J. Anal. Toxicol.*, 27: 332-341 (2003). (See Expert Report of Roger L. Bertholf, Ph.D. ("Bertholf Rept."), Ex. G (dkt. #209-7).)

(“Fenton Affidavit”) (dkt. #313-7).) Mr. Fenton is the librarian at the University of Minnesota Bio-Medical Library, who averred that the Library made the Preston Article available to the public no later than August 27, 2003, in advance of the ‘680 patent’s filing date.

Ameritox argues correctly that the affidavit is inadmissible hearsay at trial. The hearsay concern has been mitigated by Millennium’s recent response indicating that it may call Mr. Fenton as a witness if the need arises. (Def.’s 1st Am. Witness List (dkt. #372) 3.)² Even if Millennium is unable to produce Mr. Fenton as a witness at trial, the Fenton Affidavit could still be admissible under the residual exception to hearsay, Fed. R. Evid. 807, or at least considered if evidence ordinarily relied upon by a previously disclosed expert, Fed. R. Evid. 703. Alternatively, Fed. R. Evid. 902(11) provides that a business record is self-authenticating when accompanied by a written declaration by the *custodian or other qualified person* that the record in question: (1) was made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, a person with knowledge of those matters; (2) was kept in the course of the regularly conducted activity; and (3) was made by the regularly conducted activity as a regular practice. *See Thanongsinh v. Bd. of Educ.*, 462 F.3d 762, 777 (7th Cir. 2006).

Without explanation, plaintiffs argue that Mr. Fenton is not a custodian because he had “only been working at the Library since 2009” and, therefore, cannot authenticate the Preston Article. (Pl.’s Fifth Mot. (dkt. #282) 2.) What Fenton’s tenure has to do with his responsibility as custodian of records is wholly unclear, and plaintiffs point to no

² Millennium indicates that it had hoped the parties would stipulate to the admissibility (and authenticity) of the Fenton affidavit, but apparently this has not occurred.

case law to support this apparent *non sequitur*. Indeed, in *Thanongsinh*, the Seventh Circuit held that “the custodian need *not* be the individual who *personally gather[ed]* . . . [the] business record.” 462 F.3d at 777 (emphasis added) (alteration in original). Rather, the custodian “need only be familiar with the company's recordkeeping practices.” *Id.* The court finds that as librarian and business manager of the library, Fenton satisfies this threshold requirement.

Mr. Fenton’s affidavit also meets the other criteria because (1) he avers to having personal knowledge of the Library’s recordkeeping practices; (2) it attaches a “true and correct copy” of the date-stamped Preston Article received by the library; and (3) it explains the library’s practice is to affix date stamps to journal publications as the last step before they are made available to the general public. (Fenton Aff. (dkt. #313-7) ¶¶ 1-5.) The Fenton Affidavit was also prepared under oath, meeting the declaration requirement of Rule 902(11). (*See id.*) Assuming plaintiffs may cross-examine Mr. Fenton as to any of these points, particularly the last one, the affidavit appears to meet all of the requirements of Rule 902(11).³

In its response, Millennium also challenges plaintiffs’ purported new theory that the critical date is not August 28, 2003, but rather the earlier invention date (approximately May 30, 2003). (Def.’s Opp’n (dkt. #332) 9.) Millennium characterizes this as “litigation-by-ambush” because plaintiffs had given no advance notice of an earlier invention date until March 5, 2015, when the inventor Dr. Larson filed a declaration. (Dr. Michael E. M. Larson (“Larson Decl.”) (dkt. #284).) For this reason, Millennium

³ The court reserves on whether this evidence alone is enough to permit a reasonable jury to find that Preston article was “sufficiently accessible to the public interested in the art.”

argues that plaintiffs should be deemed to have waived the right to claim an earlier invention date, citing several cases to support this position. *See Promega Corp. v. Applied Biosystems, LLC*, No. 13-cv-2333, 2013 WL 2898260, at *5 (N.D. Ill. June 12, 2013) (patentee waived any argument for an earlier priority date where that patentee failed to provide any evidence of an earlier date in its interrogatory responses and failed to amend responses in timely fashion), *aff'd*, 557 F. App'x 1000 (Fed. Cir. 2014); *Sanofi-Aventis Deutschland GmbH v. Genentech, Inc.*, No. C 08-4909 SI, C 09-4919 SI, 2011 WL 839411, at *27 (N.D. Cal. Mar. 7, 2011) (holding that patentee was “barred from asserting that it is entitled to an earlier invention date” where assertion was made for the first time in opposition to summary judgment), *aff'd*, 716 F.3d 586 (Fed. Cir. 2013); *In re Katz Interactive Call Processing Patent Litig.*, Nos. 07-ML- 01816-C-RGK, CV 07-4960-RGK, 2009 WL 8636007, at *2-3 (C.D. Cal. July 28, 2009) (“To the extent that Katz believed it had a good faith basis for asserting an earlier priority date, it was obligated to do so by updating its discovery responses when it became aware of that position.”).

The court finds that the facts in each of the cases cited by Millennium are inapposite to the present case. In each case, the patentee waived an earlier priority date because the patentee failed to assert it or produce any evidence of an earlier date when called upon to do so by Fed. R. Civ. P. 37(c)(1), in response to legitimate discovery or by virtue of misleading statements to the contrary. Here, Millennium provides no evidence that plaintiffs failed to meet such an obligation to disclose an earlier filing date. While it is true that plaintiffs did refer to the August 28, 2003, filing date in their opposition to Millennium’s motion for summary judgment (*see* Pls.’ Opp’n (dkt. #172) 25), the court

can find no point where plaintiffs were obligated to provide an earlier date or otherwise placed the proverbial line in the sand for the purpose of binding their position at trial.⁴

Thus, Millennium's cries of prejudice fall flat. For some time, and at least before the close of discovery, Millennium has been made aware of discovery documents supporting an earlier filing date, as set forth in Dr. Larson's declaration. (*See generally* Larson Decl., Exs. A-C (dkt. ##284-1 to 284-3).) Millennium certainly could have sought further discovery on these issues to pin plaintiffs to a specific invention or filing date but chose not to do so. Millennium's position is not, therefore, one of prejudice, so much as one of lost opportunity. For this reason, the court will permit plaintiffs to introduce evidence of an earlier invention date.

One further, related point is worth addressing before trial. Millennium argues that whether or not Preston qualifies as prior art (for anticipation or novelty purposes), the Preston Article indicates the level of ordinary skill in the art around the time of the alleged invention, and the article can at least be offered and used to prove obviousness. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) ("Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) *the level of ordinary skill in the art*; and (4) objective indicia of nonobviousness." (emphasis added)).

⁴ At summary judgment, neither party moved on novelty or obviousness. The issue of novelty (and the invention date) is only now before the court.

Millennium points to a Federal Circuit case holding that references may be used as “indicators of the level of ordinary skill in the art,” even if they post-date the alleged invention. *See Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1581 (Fed. Cir. 1983) (“[T]he M & E criteria, though not technically prior art, were, in effect, properly used as indicators of the level of ordinary skill in the art to which the invention pertained.” (citations omitted)); *see also Disney Enters., Inc. v. Kappos*, 923 F. Supp. 2d 788, 801 (E.D. Va. 2013) (“Publications published after the date of invention have long been allowed ‘as evidence of the state of the art existing on the filing date of an application.’”) (quoting *In re Hogan*, 559 F.2d 595, 605 & n.17 (C.C.P.A. 1977)).

On a facial level, there would seem no reason why the Preston article could not be admitted for the purpose of determining obviousness. No doubt corroborating testimony will be required to ascertain what was generally known by the skilled artisan, because the contents of the entire article could hardly be considered commonly known *without more* for the simple reason that an academic journal tends to provide new insights beyond what was generally known in the scientific literature.⁵ *See In re Omeprazole Patent Litig.*, 84 F. App’x 76, 81 (Fed. Cir. 2003) (“Genpharm reads too much into *Thomas & Betts* because, unlike here, the document at issue in that case received additional support in the form of testimony about the state of art at the time of the publication. The level of skill in the art is a factual question, and the district court did not clearly err in *declining* to

⁵ To this end, Millennium and Ameritox may wish to stipulate whether the Preston article would be considered within the ordinary skill level of those in field at the time of: (a) the invention date, and (b) the filing date.

consider the Up-to-Date disclosure as reflecting the level of skill in the art.”). In any event, because the Fenton Affidavit may properly authenticate the article, and because Mr. Fenton will apparently be available to testify, the court will deny plaintiffs’ motion.

D. Sixth Motion to Exclude the George, Preston and Kell References (dkt. #285)

Plaintiffs also seek to exclude: (1) the George and Preston references for purposes of anticipation and obviousness, and (2) the Kell reference for purposes of obviousness.

i. The George Article (anticipation)

Plaintiffs challenge the use of the George Article for the purpose of proving anticipation on grounds that it is not relevant or would be confusing to the jury. *See* Fed.

R. Evid. 402, 403. In seeking this exclusion, plaintiffs point to the following:

- That the court, in the summary judgment opinion, stated that the George Article is (1) “[o]ne of the most relevant prior art references in this case” (2/19/15 Op. & Order (dkt. #215) 8); (2) that the only comparison disclosed in the George Article is a “patient’s test result to earlier results from that *same* patient” (*id.* at 10); and (3) that the George Article provides that “creatinine normalization was problematic and ‘for practical purposes . . . the only reliable method available to monitor methadone compliance is the use of plasma methadone drug testing” (*id.* at 53).
- That the George Article was the subject of extensive and repeated examination at the Patent Office. (*See, e.g.*, Rebuttal Expert Report of Dr. Paul Orsulak (dkt. #118) ¶¶ 81-83 (excerpting portions of the prosecution history to show that George was considered by three different examiners); Expert Report of Roger L. Bertholf Ph.D. (dkt. #209) ¶ 48 (acknowledging George Article was “the focus of two reexaminations” of the asserted patent).)⁶

⁶ The Patent Office concluded that one skilled in the art would interpret the George Article in relation to claim element step (f), and the related claim element step (b), as follows:

Relying on both points, plaintiffs contend that the George Article by itself cannot be found to anticipate the '680 patent because step (f) is not disclosed. Because of this, plaintiffs move the court to exclude the George Article for the purposes of Millennium's anticipation defense. For a variety of reasons, the court will deny plaintiffs' motion in limine at this time.

As Millennium rightly points out, the court's discussion of the George Article in the summary judgment opinion was limited to the specific context of *Millennium's* motion on patent (in)eligibility under § 101. Nowhere did Ameritox put Millennium to its proof regarding, nor did the court consider, Millennium's anticipation defense in light of the George Article. (2/19/15 Op. & Order (dkt. #215).) Moreover, while Dr. Orsulak was quoted as asserting that the "George Article only discloses comparing a patent's test result to earlier results from the same patient" (*id.* at 8), Millennium was under no obligation to proffer any contrary evidence with respect to step (f). *See Alice Corp. v. CLS*

Indeed in George, no comparison is made between the metabolite concentration of the 14 control subjects and the metabolite from any of the 56 drug users in order to 'quantify the concentration' of the test metabolite. Furthermore, although George suggests that data collected over time from a single individual could be used to provide the set of known normative data specific to the reference metabolite, step (b) of the claims requires the set of normative data to be collected from a '*population*' . . . The declaration filed 29 March 2013 by Dr. Michael E. convincingly asserts that one of ordinary skill in the art would understand "population" as used in the *context of the '680 patent and claims, to define a group of more than a single test subject* . . . Thus the skilled artisan would understand the term "population" as . . . a group of more than one individual.

(Bertholf Rept., Ex. 19 (dkt. #209-19) 4-5.)

Bank Int'l, 134 S. Ct. 2347, 2354–55 (2014). Because the comparative step (step (f)) lay at the core of Millennium’s defense (particularly the first prong), and because the first prong of *Alice* (abstractness) is a question of law,⁷ Millennium was not required to proffer any evidence that step (f) existed in the prior art for the purposes of its § 101 defense. Compare 2/19/15 Op. & Order (dkt. #215) 41-42, 44-57, with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1304 (2012) (“[T]he ‘wherein’ clauses simply tell a doctor about the relevant natural laws.”).

In fairness to plaintiffs, Dr. Wu opined that step (f) was routine, in addition to being an abstract mental process, but he did not opine that all six steps of the invention existed in a single prior art publication. Otherwise, presumably, Millennium would have moved for summary judgment on novelty grounds (§ 102), not just patent eligibility (§ 101). (Dr. Alan H. Wu Invalidity Report (“Wu Invalidity Rept.”) (dkt. #115) ¶ 113.) Moreover, Millennium’s response, while long on the inappropriateness and timing of plaintiffs’ sixth motion in limine, was noticeably short on showing that the George Article

⁷ Looking to the jury instructions filed to date, both parties seem to agree that the first prong of *Alice* is a question of law. (Def.’s Proposed Jury Instructions (dkt. #304) 28 (“[The court has] determined that the claims of the ’680 patent are directed to an abstract idea.”); (Pls.’ Proposed Jury Instructions (dkt. #290) 35) (“Plaintiffs do not propose a jury instruction for this issue because it is an issue for the Court, not the jury.”). Where the parties diverge is with respect to the second prong of inventive concept, see *Alice*, 134 S. Ct. at 2354–55, but even this is a mixed question of fact and law. *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009) (“As a question of law, lack of statutory subject matter is a ‘ground [for affirmance] within the power of the appellate court to formulate.’ While there may be cases in which the legal question as to patentable subject matter may turn on subsidiary factual issues, *Comiskey* has not identified any relevant fact issues that must be resolved in order to address the patentability of the subject matter of *Comiskey*’s application.”) (citations omitted.) During the final pretrial conference, it will be incumbent on the parties to advise the court of their view as to what *facts remain in dispute* for the jury to decide.

could be read to teach steps (e) and (f) of the claims in the ‘680 patent (*i.e.*, the combination). If this cannot be done to the court’s satisfaction before opening statements, the court will preclude any representation that George anticipates the ‘680 patent during opening statements.

Finally, plaintiffs’ assertion that because the George Article was the subject of extensive and repeated examination at the Patent Office, it must be excluded from any discussion on anticipation is a non-starter. Although the statutory presumption may make it “especially difficult” for Millennium to overcome the George Article because the Patent Office reviewed the reference, this does not mean that the issue is entirely *foreclosed* from jury determination. *See Impax Labs., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008). For example, Millennium *may* proffer evidence at trial that controverts what the Patent Office has found. This is a question of weight for the fact-finder, not admissibility.

ii. The Preston Article (anticipation)

Plaintiffs contend that the Preston Article should be excluded for purposes of anticipation for reasons similar to the George Article. First, because Millennium’s expert Dr. Bertholf opines that “the [George] article draws a similar conclusion” to the Preston Article, plaintiffs contend that it should “be excluded because it is cumulative.” (Pls.’ Sixth Mot. (dkt. #285) 4) (quoting Bertholf Rept. (dkt. #209) ¶ 89). If this were plaintiffs’ only basis for objecting to the use of the Preston Article for purposes of anticipation, the motion would border on the frivolous. While the court is all for

streamlining the trial, the notion that a defendant can submit only one piece of prior art to show anticipation is ludicrous.

However, plaintiffs also argue that the Preston Article “cannot anticipate because it does not disclose the comparison of step (f).” (Pls.’ Sixth Mot. (dkt. #285) 5) Millennium counters that “[w]hile the parties may dispute whether the George Article expressly discloses a step (f) comparison, there can be no question that the Preston Article expressly discloses the comparison of step (f).” (Def.’s Opp’n (dkt. # 333) 6.) Millennium supports this position with a quote from the Preston Article: “The present data should be useful to clinicians as a *comparison* for their outpatients’ immunoassay results and to scientists as a basis for addressing the potential utility of urine test for monitoring compliance with methadone maintenance.” (Bertholf Rept. (dkt. #209) 8.)

Much like George, it is not entirely clear how the Preston passage discloses step (f) of the ’680 patent. Millennium’s response also provides no real explanation as to on how its expert Dr. Bertholf equates the disclosure of a comparison of an individual patient’s results over time with the disclosure of a comparison with a population of patients’ normative results. This creates the same level of doubt as to whether the Preston Article is relevant to the issue of anticipation as the George Article. As with George, what tips the scales is that the issue was not raised in a motion for summary judgment. *See* Fed. R. Civ. P. 56(a)-(f). Had it been, Millennium would have been expected to come forward with meaningful rebuttal evidence to ensure that the factual issue on anticipation -- whether the Preston Article discloses step (f) -- is disputed, and worthy of jury determination.

Accordingly, because a motion in limine is an inappropriate forum to consider this issue, and because the court declines plaintiffs' offer to invite a Rule 56 (f) response from Millennium at this late date,⁸ the court will deny Ameritox's motion in limine at this time and give Millennium an opportunity to explain at the final pretrial conference why any statement as to the article anticipating the '680 patent should be allowed during opening statements. (Def.'s Opp'n (dkt. #333) 6.)

iii. The George, Preston and Kell References (obviousness)

Plaintiffs' sweeping motion in limine as to the relevance of George, Preston and Kell for purposes of obviousness is even more premature. Broadly speaking, plaintiffs contend that all three references -- in isolation or when combined with other references in the record -- should be excluded because they *teach away* from the comparison of step (f). *See Illumina Inc. v. Complete Genomics Inc.*, No. 10-cv-05542, 2013 WL 1282977, at *17 (N.D. Cal. Mar. 26, 2013) ("If a prior art reference 'teaches away' from an invention, that invention is not made obvious by the prior art."). While the court has reviewed the George Article in prior opinions, including noting that it teaches away from the use of creatinine for normalizing urine samples, that analysis was limited to the summary judgment opinion on the issue of patent eligibility. (2/19/15 Op. & Order (dkt. #215) 9-10.) Certainly, Millennium should by now be on notice that any evidence proffered at trial will need to be relatively strong to undermine the express teachings in the George

⁸ In its motion, plaintiffs stated in a footnote: "While the Court could exclude George, Preston, and Kell on evidentiary grounds, the Court would also be well within its discretion to convert this motion to a motion for summary judgment because Millennium has notice and a reasonable time to respond." (Pls.' Sixth Mot. (dkt. #285) 3 n.1.)

Article. (*Id.* at 10 (“[T]here is too large of an interindividual variation to use urinary excretion concentrations of methadone or EDDP as markers of compliance”; urinary excretion testing “would point to a lack of suitability of using urine concentrations of EDDP or methadone as markers of compliance”; and “the only reliable method available to monitor methadone compliance is the use of plasma methadone drug testing.”).) A similarly strong showing would also be required with respect to the Preston and Kell references, if plaintiffs are correct in contending that those references teach away from the use of creatinine as well. Once again, however, if plaintiffs wanted a summary judgment ruling on this issue, they should have put Millennium to its proof by the deadline for dispositive motions.

Moreover, whether a reference teaches away from a claimed invention is an issue of fact for the jury. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“As with other subsidiary obviousness inquiries, ‘[w]hat a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact.’” (citation omitted)). As the Federal Circuit explained, “obviousness must be determined in light of all the facts, and there is no rule that a single reference that teaches away will mandate a finding of nonobviousness.” *Id.*⁹ This case is no exception, particularly when plaintiffs seek to dispose of the obviousness issue *not* by way of a summary judgment motion, but by way of motion in limine.

⁹ In this case, there are several references that teach away, not just a single one -- so *Medichem* perhaps has less persuasive weight. But given that the court has yet to hear testimony from Millennium’s expert(s) on obviousness, the more prudent approach is to allow all three references come in for the purposes of obviousness at this time.

Accordingly, the court denies Ameritox's motion to exclude all three references as to obviousness at this time. Given the case law, the court will also not preclude Millennium from referencing its obviousness defense in opening statements.¹⁰

E. Thirteenth Motion to Exclude Evidence of Commercial Success During the Liability Phase (dkt. #295)

Next, plaintiffs seek to exclude argument or evidence concerning the commercial success of their products or concerning the means by which they allegedly achieved that success during the liability phase of the trial. Typically, a patentee is the party seeking to proffer evidence of commercial success to show non-obviousness. Here, the opposite is true: plaintiffs are arguing that Millennium should be precluded from proffering any evidence of commercial success. Plaintiffs represent that this evidence would include without limitation (1) the 2010 Bain Study, (2) Ameritox's salesforce.com data, (3) Millennium's test drive data, (4) pleadings from a prior false advertising case between Ameritox and Millennium, (5) expert testimony or reports from the prior Florida litigation, (6) testimony from Millennium witnesses concerning Millennium's commercial success or marketing messaging, (7) Millennium's website, (8) Appendix 5 to the Bero

¹⁰ Because the issue of patent eligibility is decided under a different standard than obviousness -- requiring that the additional element or combination of elements be "well known" in the art, not simply known -- Millennium may want to refrain voluntarily from referencing its patent eligibility defense in its opening statement in recognition that the court might ultimately conclude that no reasonable jury could find in its favor on that defense on the record at trial. *See Mayo*, 132 S. Ct. at 1298 (explaining the requirement for "well understood, routine, conventional activity previously engaged in by scientists who work in the field" when undertaking the inventive concept analysis).

Report (dkt. #237-10), and (9) Bero's commercial success expert report and the evidence cited therein (Expert Report of Richard F. Bero (dkt. #263)).

Consistent with the limited case law on this subject, *see Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993) (while "indicia of non-obviousness" weigh in favor of finding non-obviousness, "the lack of such evidence does not weigh in favor of obviousness"), Millennium consents to this outcome.¹¹ (Def.'s Opp'n (dkt. # 354) 24.) At the same time, Millennium states that "[e]vidence such as testimony from Millennium witnesses regarding marketing messaging, as well as pleadings from previous false advertising litigation are relevant to rebut any copying theory presented at trial by explaining that Millennium was positioning itself as *different* from Ameritox, not copying RX Guardian CD, the science and technology of which Millennium was challenging in court and in the marketplace." (*Id.* at 24-25.) Accordingly, the court will grant plaintiffs' motion to the extent that Ameritox does not open the door by proffering evidence on commercial success or copying.

F. Plaintiffs' Motion to Exclude Millennium's Expert: Alan H. Wu, PH.D. (dkt. #246)

Ameritox seeks to exclude Dr. Wu from testifying at trial. The admissibility of expert testimony in federal courts is governed principally by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides:

¹¹ The court addresses whether evidence of commercial success may be admissible in the second phase of trial below. *See infra* Sections III.A., III.B., VI.A.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

A district court functions as a “gatekeeper” regarding expert testimony; the court must determine whether a party's proffered expert testimony is relevant and reliable. *Daubert*, 509 U.S. at 589; *see also United States v. Johnsted*, 30 F. Supp. 3d 814, 816 (W.D. Wis. 2013) (the expert testimony must be “not only relevant, but reliable.”). Although expert testimony is “liberally admissible under the Federal Rules of Evidence,” *Lyman v. St. Jude Med. S.C., Inc.*, 580 F. Supp. 2d 719, 723 (E.D. Wis. 2008), it must nevertheless satisfy the following three-part test:

- (1) the witness must be qualified “as an expert by knowledge, skill, experience, training, or education,” Fed. R. Evid. 702;
- (2) the expert's reasoning or methodology underlying the testimony must be scientifically reliable, *Daubert*, 509 U.S. at 592-93; and
- (3) the testimony must assist the trier of fact to understand the evidence or to determine a fact in issue. Fed. R. Evid. 702.

Ervin v. Johnson & Johnson, Inc., 492 F.3d 901, 904 (7th Cir. 2007). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of

proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

Plaintiffs argue that Dr. Wu’s opinions should be excluded under Federal Rule of Evidence 702 because they are “fundamentally unreliable.” (Pls.’ Br. (dkt #247) 3.) Because many of the opinions originally proffered by Dr. Wu have been rendered moot by the court’s summary judgment opinion, “Dr. Wu’s testimony will now be limited in scope.” (Def.’s Opp’n (dkt. # 351) 2.)¹² Specifically, Millennium consents to his testimony being restricted to just two areas: (1) patentable subject matter, and (2) the limited purpose of defending against Ameritox’s case for willful infringement with regard to the reasonableness of his claim construction and non-infringement opinions. (*Id.*) Still, plaintiffs take issue with the reliability of these remaining opinions.

Before addressing whether Dr. Wu’s opinions in these areas are reliable, some context is appropriate. With respect to patentable subject matter, Dr. Wu generally opined on creatinine normalization, the sources of variability in urine drug concentrations and the capabilities of urine drug testing. (Dr. Alan H. Wu Invalidity Report (“Wu Invalidity Rept.”) (dkt. #115) ¶¶ 59-85.) He also opined that creatinine normalization of urine samples was generally known at the time of the ’680 patent. (*Id.* at ¶ 112.) These opinions are certainly relevant to remaining issues of patentability and non-infringement.

¹² Specifically, Millennium has determined “not to present its defenses of inequitable conduct, waiver, laches, license and release, as well as defenses predicated on Millennium’s proposed claim construction, including indefiniteness, enablement and utility, following assessment of the Court’s recent summary judgment orders and its claim construction determinations.” (Def.’s Opp’n (dkt. #329) 1.)

Dr. Wu's evidence regarding claim construction and non-infringement -- in support of Millennium's defense to willful infringement -- is also relevant. Although Dr. Wu's claim constructions were rejected at summary judgment, the Federal Circuit has held that reasonable claim constructions -- even if not adopted -- can show that there is no objectively high likelihood of infringement. *See Cohesive Techs*, 543 F.3d at 1374 (finding no willful infringement, despite rejecting defendant's claim construction, where that construction was reasonable "in light of the specification and prosecution history"); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 747 F. Supp. 2d 1063, 1113 (W.D. Wis. 2010).¹³

Because Dr. Wu's opinions would be relevant for the limited purposes that Millennium now proposes to advance them, the court turns to whether his evidence is reliable and the specific reasons plaintiffs advance to exclude them. *First*, plaintiffs argue that Dr. Wu is biased based on a theory that he had been a colleague of Millennium's former laboratory director, Dr. Amadeo Pesce. (Pls.' Mot. (dkt. #246) 5.) In reviewing the parties' materials, there is simply no support in the case law for excluding an expert based on bias of this nature. The best that Ameritox can muster is a law digest. *See* Robert A. Matthews, Jr., *Annotated Patent Digest*, § 44:43.150 (2014). Not only is this reference unpersuasive, it runs counter to other, more persuasive authorities: "[I]t is well-established that an expert's bias is not a proper basis to bar testimony under *Daubert*."

¹³ Of course, to the extent that Dr. Wu is giving evidence with respect to the objective prong of willfulness, that prong will be examined solely by the court, somewhat ameliorating plaintiffs' concerns as to admissibility or at least allowing the court to hear testimony before ruling on admissibility.

See Cage v. City of Chi., 979 F. Supp. 2d 787, 827 (N.D. Ill. 2013) (citing *DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000)); *see also In re Unisys Savings Plan Litig.*, 173 F.3d 145, 166 n.11 (3d Cir. 1999) (“Courts have held in numerous other cases that credibility is irrelevant to determining whether a proposed expert witness’s testimony is admissible under Rule 702, and particularly whether it is based on reliable methodology For example, expert witnesses cannot be excluded on the basis of bias.” (citations omitted)).¹⁴ Moreover, during his deposition, Dr. Wu flatly denied the accusation of bias and stated that he had not even discussed his opinions with Dr. Pesce. (01/30/15 Wu Dep. (dkt. #205) 89:12-21 (“Q. Did your relationship with Dr. Pesce impact your opinions in this case? A. No.”).) As such, plaintiffs’ motion to exclude Wu’s testimony on the basis of bias is essentially frivolous.¹⁵

Second, plaintiffs contend that Dr. Wu’s opinions are unreliable because he estimated that he only spent thirty hours working on the case. (*Id.* at 70:17-21.) Based on this estimate, plaintiffs speculate that Dr. Wu’s opinions cannot be his own and, thus, are unreliable. Again, this argument is void of citation to case law, which is hardly surprising since case law suggests that the amount of time Dr. Wu spent on this case is

¹⁴ Further, plaintiffs argue bias based on the fact that Dr. Wu is the laboratory director for a pain management practice -- the Puana Pain Management Group -- that uses Millennium as its reference laboratory, among other relatively insignificant accusations of bias. (Pls.’ Br. (dkt. #247) 5.) Not only is the evidence of bias weak, but any evidence of bias would again simply go to weight and does not serve as a basis to exclude Dr. Wu’s testimony.

¹⁵ The court is hopeful that counsels’ predilection on both sides to “throw in the kitchen sink” will end with their overblown motions in limine and unfiltered exhibit lists. Regardless, the court *will* end any failure to reasonably narrow and refine their submissions to the jury.

not a proper ground for exclusion. *See Ernst v. City of Chi.*, 39 F. Supp. 3d 1005, 1011 (N.D. Ill. 2014) (“The thoroughness of [an expert’s preparation] goes to the weight of his testimony rather than its admissibility.” (citation omitted)). Particularly given that plaintiffs do not dispute that Dr. Wu *did* spend 30 hours on his opinions in this matter, the holding in *Ernst* generally seems sensible and certainly seems reasonable here.

Third, plaintiffs contend that Dr. Wu’s inability to recall at deposition a specific document -- the reexamination certificate of the ’680 patent -- necessarily means that he did not independently form his opinions or draft his expert reports. (Pls.’ Br. (dkt. #247) 8-11.) As an initial matter, this accusation does not entirely match the record. Throughout the deposition, Dr. Wu testified that he was aware the patents-in-suit underwent reexamination. (*See, e.g.*, 01/30/15 Wu Dep. (dkt. #205) 182:4-7.) Dr. Wu also testified that he had considered claims added during reexamination as part of his analysis. (*Id.* at 213:1-17.)¹⁶

Even if Dr. Wu were unaware of the reexamination certificate, his inability to recall the reexamination certificate would have marginal (if any) bearing on his opinions under § 101 since the parties’ dispute on patent eligibility centered on claim 1 (which was not amended during the reexamination process with respect to the ’680 patent). And again, whether his opinions should be excluded for the purposes of the objective

¹⁶ Dr. Wu’s expert report also states that he considered the claims added during the reexaminations of the patents-in-suit. (Dr. Alan H. Wu Rebuttal Report (“Wu Rebuttal Rept.”) (dkt. #116) ¶¶ 62-70, 79-87) (assessing non-infringement of claims added during reexaminations of the patents-in-suit).)

prong regarding willfulness, is mollified by the fact that this prong will not be heard by the jury. *See supra* Section II.B.; *infra* Section IV.A.

Fourth, plaintiffs cite to testimony by Dr. Wu indicating confusion as to certain legal terms and regarding areas in which he did not render opinions in his expert reports. The court also finds such confusion more an issue of weight, than of exclusion. *See Sunbeam Prods., Inc. v. Homedics, Inc.*, 670 F. Supp. 2d 873, 882-83 (W.D. Wis. 2009), *aff'd*, 412 F. App'x 263 (Fed. Cir. 2010). To address briefly just one of the challenges going to this issue, plaintiffs question Dr. Wu's overall reliability because he "didn't know" the meaning of certain claim steps or claim terms.¹⁷ (Pls.' Br. (dkt. #247) 7-8, 16-17.) As a result, plaintiffs now assert that Dr. Wu's non-infringement opinions are unreliable because he consistently opined that step (f) of the '680 claim is indefinite, but did not know what the plain and ordinary meaning of step (f) was.

The court finds this attack essentially frivolous as well. During deposition, Dr. Wu indicated that he only understood step (f) as meaning a dose or dose range. (01/30/15 Wu Dep. (dkt. #205) 218:16-219:1 ("Q. Do you have an opinion if Millennium practices step (f) of the asserted claims of the Larson's patent if the court does not adopt your proposed claimed construction? A. If the court does not adopt my interpretation that [step] (f) means finding a dose or a dose range, then I would have to be told what [step] (f) means because it then becomes ambiguous. And, therefore, without knowing what [step] (f) means, I can't answer your question.").) In short, Dr.

¹⁷ Ameritox also pedantically argues that because Dr. Wu did not give opinions on anticipation and obviousness in his report, his deposition testimony stating that he did renders him unreliable.

Wu rendered no opinion on the plain and ordinary meaning of step (f) except that step (f) was dose specific. Naturally, he found step (f) was indefinite. (Wu Invalidity Rept. (dkt. #115) ¶ 26.) Because of this, there was no inconsistency between his expert report and his deposition testimony. Indeed, the fact that Dr. Wu did not view the claims as having meaning (other than “dose specific”) could be relevant for the “limited purpose of demonstrating the reasonableness of Millennium’s interpretation of the ’680 patent claims upon which a noninfringement determination would be based.” (Def.’s Opp’n (dkt. # 351) 12); *see also Douglas Dynamics*, 747 F. Supp. 2d at 1113 (“[b]ecause the claim language was susceptible to Buyers’ reasonable construction and acceptance of that construction at most would have led to a finding of noninfringement (and at least have created a very close call on infringement), there was no objectively high likelihood of infringement.”)).

Fifth, plaintiffs contend that Dr. Wu’s opinions should be excluded as unreliable because allegedly (1) Millennium selected the materials reviewed by Dr. Wu in forming his opinions and (2) he conducted no independent investigation of the facts underlying his opinions. (Pls.’ Br. (dkt. #247) 11-12.) As an initial matter, Millennium did not select all of the materials Dr. Wu reviewed. As he explained at deposition, Dr. Wu asked for “additional documents that [he] felt were necessary, or at least asked if they existed.” (01/30/15 Wu Dep. (dkt. #205) 62:11-16.) Even if Dr. Wu had only reviewed documents provided by Millennium’s counsel, that alone would not render his opinions so unreliable that they should be excluded. The case law cited in plaintiffs’ own brief states as much. *See R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 269 (S.D.N.Y. 2010)

(“Defendants urge that the testimony of plaintiff’s expert is inherently unreliable because plaintiff’s counsel provided almost all of the data on which they based their opinions Unless the information or assumptions that plaintiff’s experts relied on were ‘so unrealistic and contradictory as to suggest bad faith,’ inaccuracies in the underlying assumptions do not generally render an expert’s testimony inadmissible.”) (citing *Zerega Ave. Realty Corp. v. Hornbeck Offshore Transp., LLC*, 571 F.3d 206, 214 (2d Cir. 2009)). Since there is nothing in plaintiffs’ submissions supporting a finding of “bad faith,” any notion that Dr. Wu’s opinions must be excluded because Millennium selected materials for him to consider in forming his opinion is without merit.

Plaintiffs’ additional argument is that Dr. Wu’s opinions are unreliable because he conducted no independent investigation since he acknowledged not doing any such investigation. (01/30/15 Wu Dep. (dkt. #205) 44:9-14. (“Q. What research or investigation have you performed in the context of this litigation? A. I’ve done no research in the context of this investigation. I have rendered opinions.”).) Notwithstanding this, Dr. Wu is free to testify why this was not necessary, as well as to his requests for Millennium to run literature searches on his behalf. (01/30/15 Wu Dep. (dkt. #205) 63:17-64:24.)

The request for such searches demonstrates independent thought and cuts against plaintiffs’ theory that he “considered only Millennium’s cherry-picked information to parrot Millennium’s beliefs.” (Pl’s Br. (dkt #247) 11.) But even if he failed to request the searches, and only accepted information provided by Millennium, the case law suggests that this concern also goes to weight, “rather than . . . admissibility.” *NutraSweet Co. v.*

X-L Eng'g Co., 227 F.3d 776, 789 (7th Cir. 2000) (expert used data obtained by plaintiff's hydrologists rather than data he generated himself, creating an issue of weight, not admissibility).¹⁸

Sixth, plaintiffs make one final argument styled as a 'catch all' that essentially accuses Dr. Wu of allowing his report to be ghost-written. (*See, e.g.*, Pls.' Br. (dkt #247) 8 (discussing "Wu's substantial lack of participation in forming his opinions or drafting his expert reports").) This accusation stems largely from testimony already addressed above. There is, however, no evidence in the record that would justify striking Dr. Wu's report altogether. To justify that result, plaintiffs would have to show that Millennium exerted some level of undue influence or that Dr. Wu signed the opinion to appease Millennium. *See Trigon Ins. Co. v. United States*, 204 F.R.D. 277, 292 (E.D. Va. 2001) (a "distinction [exists] between those opinions that an expert 'freely authorized and adopted as his own' and those that are done 'merely for appeasement or because of intimidation or some undue influence by the party or counsel who has retained him.'").

¹⁸ The other cases that plaintiffs cite addressing this point are unavailing. Not only were they district court cases from other circuits, but none was set in the context of patent invalidity. *Cf. R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 257 (S.D.N.Y. 2010) (involves expert calculating damages and not reviewing materials beyond those provided by counsel); *State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 3:08-CV-436, 2013 WL 5770343, at *5 (N.D. Ind. June 17, 2013) (expert calculating damages attributable to fires caused by electrical goods where expert failed to verify data and cross-reference with other sources); *Hot Wax, Inc. v. Warsaw Chem. Co.*, 45 F. Supp. 2d 635, 638 (N.D. Ill. 1999) (expert being informed of a position by defendant's company and basing his report that wax existed in defendant's product without further testing or verification).

That evidence does not exist here.¹⁹ Accordingly, Dr. Wu will be permitted to testify at trial consistent with his written report.

III. Millennium's Damages Defense

A. Motion to Exclude the Expert Testimony of Richard F. Bero, CPA, CVA Proffered by Millennium Health, LLC (dkt. #274)

Plaintiffs seek to exclude the testimony of Millennium's damages expert Richard Bero as unreliable and irrelevant under Rule 702 and *Daubert*. Plaintiffs' challenge centers on Bero's analysis of the *Georgia-Pacific* factors and his conclusion of a reasonable royalty rate in a hypothetical negotiation, positing three reasons to exclude Bero's testimony in whole or in part.

First, plaintiffs contend that Bero's testimony on non-infringing alternatives to Millennium's RADAR report should be excluded because (1) he failed to prove the existence of non-infringing alternatives available on the market during the time of the hypothetical negotiation; and (2) Millennium admits no non-infringing alternatives exist. In addition to the fifteen *Georgia-Pacific* factors, plaintiffs acknowledge that a jury may also consider the existence of non-infringing alternatives when determining a reasonable royalty. *See Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1571-72 (Fed. Cir. 1996). This is in recognition of the fact that an infringer in a hypothetical negotiation "would have been in a stronger position to negotiate for a lower royalty rate knowing it had a competitive noninfringing device 'in the wings.'" *Id.* Importantly, it is plaintiffs' burden to show a

¹⁹ Plaintiffs' cases are wholly inapposite. *See, e.g., Numatics, Inc. v. Balluff, Inc.*, No. 13-11049, 2014 WL 7211167, at *5 (E.D. Mich. Dec. 16, 2014) (the expert admitted that counsel actually typed the expert's reports and the stricken report adopted discovery responses and invalidity contentions verbatim).

lack of noninfringing alternatives. *Cohesive Techs., Inc.* 543 F.3d at 1373 (“[T]he patent owner must show either that (1) the purchasers in the marketplace generally were willing to buy the patented product for its advantages, or (2) the specific purchasers of the infringing product purchased on that basis.”) (quoting *Standard Hvens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991)).

Millennium argues that plaintiffs are conflating two distinct questions: (1) whether there is no design-around for the patent-in-suit and (2) whether there is no non-infringing substitute. In support, Millennium specifically takes issue with plaintiffs’ reliance on certain deposition testimony of Millennium’s President:

Q. Does Millennium understand what steps would be required or necessary to design around the patents-in-suit?

...

A. Again, that’s a hard question to answer, because we haven’t done any work to do any design-around.

(Deposition of Howard Appel (dkt. #201) 66; *see also* Pls.’ Mot. to Exclude Bero, Ex. D (dkt. #275-4) (responding to interrogatory 24: “Millennium states that it has not attempted to design-around the patents-in-suit.”).) As Millennium correctly points out, this testimony concerned Millennium’s efforts to design around the patents in suit, not whether there were non-infringing alternatives. (Def.’s Resp. (dkt. #354) 9 p.5.) As such, the court rejects plaintiffs’ argument that Millennium has somehow conceded that there are no non-infringing alternatives.

Relatedly, Millennium is right to criticize plaintiffs’ position that the “only possible acceptable noninfringing substitute would be a urine drug test report delivering

range-based results.” (Def.’s Opp’n (dkt. #354) 9.) “[A] noninfringing substitute need not have the patented feature in order to be deemed ‘acceptable.’” *Apple, Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846-LHK, 2013 WL 5958178, at *2 (N.D. Cal. Nov. 7, 2013); *see also SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1166 (Fed. Cir. 1991) (“[Plaintiff] argues in effect that the noninfringing products lacked one or more features of the patented invention and, therefore, would not be deemed part of the market. However, by definition, noninfringing products do not represent an embodiment of the invention.”). Still, plaintiffs are correct in asserting that “buyers must view the substitute as equivalent to the patented device.” (Pls.’ Br. (dkt. #275) 7 (quoting *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1270 (Fed. Cir. 2008)).)

Whether the jury will accept Millennium’s RADAR report *without* graphed results of a normalized population of comparable drug users as a noninfringing alternative is not for the court to determine. *See Am. Seating Co.*, 514 F.3d at 1270. Rather, it will be up to the jury to determine whether the RADAR report within the range-based results “possess[es] characteristics significantly different” from the patented product so as not to be an acceptable substitute. *Cent. Soya Co., Inc. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1579 n.4 (Fed. Cir. 1983). At least at this stage, Millennium has also put forth sufficient evidence that it sells a product without the graphed or range-based results to allow Bero’s testimony about the availability of this purported non-infringing alternative to go to the jury. (Def.’s Opp’n (dkt. #354) 12.) Accordingly, the court rejects Ameritox’s first basis for excluding Bero’s testimony.

Second, plaintiffs take issue with Bero’s lump-sum annual royalty analysis, arguing that Bero improperly converted a running royalty as the starting point for determining a reasonable royalty under a hypothetical negotiation. The first two *Georgia-Pacific* factors consider “[t]he royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty” and “[t]he rates paid by the licensee for the use of other patents comparable to the patent-in-suit.” 318 F. Supp. at 1120. Under these factors, however, the trier of fact may decide “whether the licensor and licensee would have agreed to a lump-sum payment or instead to a running royalty based on ongoing sales or usage.” *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1326 (Fed. Cir. 2009).

As the *Lucent* court explained, there are “[s]ignificant differences” between a running royalty license and a lump-sum license, in part because under the latter, “the licensee is obligated to pay the entire, agreed-upon amount for the licensed technology, regardless of whether the technology is commercially successful or even used.” *Id.* On the flip side, if the licensed technology is “wildly successful, . . . the licensee may have acquired the technology for far less than what later proved to be its economic value.” *Id.*

In reaching his opinion, Bero relied on the lump-sum annual royalty for the infringed product entered into between Ameritox and Marshfield Clinic. In contrast, Ameritox’s expert as described below relies on a running royalty licensing arrangement with U.D. Testing, Inc. *See supra* Section IV.B. Plaintiffs argue that Ameritox assumed certain risk in entering into the licensing agreement with Marshfield Clinic on the patent in suit, resulting in “Ameritox paying less expensive royalties to Marshfield than it was

paying to U.D. Testing.” (Pls.’ Br. (dkt. #275) 13.) As an initial matter, Millennium is correct to point out that the Marshfield licensing agreement is different from the traditional lump-sum royalty challenged in other cases. The Marshfield licensing agreement involves smaller payments on an annual basis, rather than an up-front lump sum payment. Even putting this distinction aside, plaintiffs are free to present to the jury their argument that Bero failed to account for the risk involved in the Marshfield licensing agreement in converting that licensing arrangement to a running royalty rate, but that does not render Bero’s opinion unreliable; rather, any criticisms of relying on a licensing agreement which provided for annual lump-sum payments are ripe grounds for cross-examination and go to the weight to be given Bero’s testimony by the jury.²⁰

Plaintiffs also take issue with Bero’s methodology in converting a lump-sum annual royalty license to a running royalty. The focus of this argument again concerns whether Bero adequately considered the risk assumed by Ameritox in entering into the licensing agreement with Marshfield. So, too, is the court’s ruling: while fodder for cross-examination, this criticism does not render Bero’s report unreliable or otherwise serve as a basis for excluding his testimony under Rule 702 or *Daubert*. Ultimately, it will be for Bero to explain, and the parties to argue over, whether that agreement applies to the facts of this case. *Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 30 (Fed. Cir. 2012) (“[L]ump sum payments similarly should not support running royalty rates without testimony explaining how they apply to the facts of the case.”).

²⁰ This is yet another example of a fairly rudimentary principle of evidence. The court will expect more of counsel going forward.

Third, related to plaintiffs' motions to exclude evidence on commercial success (dkt. ##294, 296), plaintiffs seek to exclude Bero's testimony on the lack of commercial success of Ameritox's Guardian Rx CD product. If the court allows commercial success testimony generally, plaintiffs contend in the alternative that the court should still exclude testimony on the commercial success of the Guardian product as unreliable, since Bero simply adopted another expert's opinions without conducting any independent investigation. Bero, however, testified at his deposition to his (or his office's) analysis of the data provided in the other expert's report, and indicated in his own report that he reviewed other experts' reports, including those of plaintiffs' experts, in reaching his conclusions on the commercial success (or lack thereof) of Ameritox's products, presumably including Guardian. (Def.'s Opp'n (dkt. #354) 19.) Moreover, as an expert, Bero can rely on information for which he does not have first-hand knowledge. *See Daubert*, 509 U.S. at 592 ("Unlike an ordinary witness, *see* Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge.").

Finally, plaintiffs argue that evidence as to Factor 8 of the *Georgia-Pacific* analysis (concerning the profitability of the patented product, its commercial success and its current popularity) should be excluded on relevance grounds because both experts opine that the factor is neutral. While Millennium concedes that there is no dispute as to the weight that should be given this factor, the court agrees with Millennium that Bero's testimony on this factor is still relevant because "even though [both experts] concluded the factor was neutral in their own analysis, it is not necessarily the case that Millennium

agrees that the factor is neutral in relation to the starting point of Plaintiffs' expert." (Def.'s Opp'n (dkt. #354) 21.) Moreover, the jury is allowed to weigh the credibility and analysis of the sides' experts on all Georgia-Pacific factors, including those on which they may ultimately agree.

Accordingly, the court will deny Ameritox's motion to exclude the testimony of Millennium's damages expert Richard Bero.

B. Twelfth Motion in Limine: Preclude Both Parties from Presenting Evidence Concerning Georgia-Pacific Factor 8 (dkt. #294)

As explained above, Ameritox also seeks an order precluding both parties from presenting evidence concerning *Georgia-Pacific* Factor 8. For the reasons explained above, the court agrees with Millennium that even though both experts find this factor to be neutral, Millennium's expert should be allowed to describe how the factor is *not* neutral with respect to Ameritox's starting royalty rate of \$6.00 per accused sample.

As for plaintiffs' concern that this evidence will turn into a "sideshow involving tangential issues already litigated in the prior Florida litigation" (Pls.' Twelfth Mot. (dkt. #294) 3), it is largely unwarranted. As far as the court can discern, Factor 8 concerns the patented product's commercial success at the time of the start of infringement, *not* the infringing product's subsequent commercial success, and therefore Millennium's subsequent market performance and the reasons for that performance are not relevant, at least with respect to that factor. Of course, Millennium's success in selling the RADAR reports and the reasons for that success -- in particular, the disputed importance of non-patented components of the invention -- are relevant to Factor 13 (concerning the

portion of profits attributable to the patented invention), but that “sideshow” is not avoided by excluding evidence as to Factor 8; in any event, the court will expect counsel to be as brief and to the point as possible on all factual issues at trial, and it will entertain cumulative or relevance objections if any party goes too far afield or is repetitive. The court sees no basis for excluding *all* evidence on this factor before trial, however. Accordingly, the court will deny Ameritox’s twelfth motion in limine as well.

C. Fourteenth Motion In Limine: Exclude Millennium’s Test Drive Data (dkt. #296)

Citing to Federal Rules of Evidence 403, 802 and 803, plaintiffs seek an order excluding evidence of customers’ opinions based on “test drives” of Millennium’s RADAR report product. Beginning in 2009, Millennium offered these “test drives” so that the potential customer could appreciate the service Millennium offers. The results of these test drives -- whether the potential customer chose Millennium or another laboratory and the reason or reasons for the customer’s decision -- were collected in spreadsheets. (Declaration of Mark T. Smith, Ex. O (dkt. #307-15).) Given customer statements suggesting that turnaround time, customer service, and the ability to test with less urine were the drivers for customers’ decisions, Millennium points out that the “graphed results” are mentioned only three times in 435 lines of test drive information. (Def.’s Opp’n (dkt. #338) 3.) Millennium’s damages expert Bero relied in part on this data, along with other sources of information, to opine that customers select

Millennium's RADAR report for other reasons than the graphed results. Millennium contends that this information is pertinent to Factor 8 of the *Georgia-Pacific* factors.²¹

Plaintiffs contend that this "data presents two levels of hearsay: (1) the customer's statement to a Millennium sales representative, and (2) the sales representative's entries into the spreadsheet." (Pls.' Fourteenth Mot. (dkt. #296) 2.) As to the customer's statements, plaintiffs simply argue the statements do not fall within any of the hearsay exceptions. In response, Millennium directs the court to cases in which courts, including the Seventh Circuit, have held that customer survey responses fall within the state of mind exception to hearsay under Federal Rule of Evidence 803(3). *See Grove Fresh Distribs., Inc. v. New Eng. Apple Prods. Co.*, 969 F.2d 552, 556 (7th Cir. 1992); *see generally* 6 McCarthy on Trademarks and Unfair Competition § 32:168 (4th ed. 2014) ("[C]ases are now unanimous that evidence of the state of mind of persons surveyed is not inadmissible as hearsay."). (*See also* Def.'s Opp'n (dkt. #338) 6 (citing cases).) As Millennium also argues, the customer statements need not be admitted for the truth of the matter asserted to be probative. Instead, the evidence collected up until June 2011 (the date of the hypothetical negotiation) could be relevant to "demonstrating Millennium's understanding of market drivers" going into negotiations, regardless of whether the customers' purported reasons for selecting Millennium or one of its competitors were the true reasons. (*Id.* at 8.)

As for the second basis, plaintiffs anticipate Millennium's response that the spreadsheet itself falls within the business record exception under Rule 803(6), arguing

²¹ Once again, the court questions whether this evidence goes to Factor 8, but still finds it arguably relevant to the jury's consideration of Factor 13.

instead that the evidence is “anecdotal, subjective, unverified and unused” and, therefore, is not “trustworthy.” (Pls.’ Fourteenth Mot. (dkt. #296) 3.) While the spreadsheets may contain anecdotal and subjective information that Millennium’s President does not use in the course of his duties, Millennium represents that it will present evidence through a qualified witness that the test drive spreadsheets were “made at or near the time by -- or from information transmitted by -- someone with knowledge,” were “kept in the course of a regularly conducted activity of” Millennium, and were made as “a regular practice” of Millennium. (Def.’s Opp’n (dkt. #338) 8-9.) Assuming Millennium can lay this foundation, the court sees no basis to prohibit consideration of this evidence altogether, although plaintiffs are welcome to challenge its probative value given the arguable incentive that Millennium had even then to elicit helpful responses.

D. Eighth Motion in Limine: Exclude Argument that Removing the Infringing Graphed Results is a Non-Infringing Substitute and Evidence of Millennium’s Alleged “Revised Report” (dkt. #287)

Plaintiffs seek an order barring Millennium from introducing into evidence revised RADAR reports, which consistently offer no graphed results, or otherwise arguing to the jury that these revised reports are an acceptable non-infringing alternative. Plaintiffs posit three core reasons for this motion: (1) the RADAR report without the comparative graph does not constitute a non-infringing substitute or alternative; (2) Millennium failed to disclose this revised graph before the close of discovery; and (3) any probative value of these reports would be outweighed by unfair prejudice to Ameritox and confusion of the jury.

On the first issue, as explained above, whether the RADAR report without the comparative graph constitutes an acceptable substitute is a question of fact for the jury to consider.²² *See supra* Section III.A. While plaintiffs maintain that customers buy the RADAR Report for that comparative graph, Millennium represents that 54% of issued RADAR reports do not contain the accused graph. (Def.'s Opp'n (dkt. #334) 4 (citing Declaration of Mark T. Smith, Ex. J (dkt. #307-10) Suppl. Answ. No. 7); *see also* Declaration of Rebecca Mandel, Ex. 18 (dkt. #360-18).) Ultimately, it will be up to the jury to decide whether reports without comparative graphs constitute acceptable substitutes.

Millennium also seeks to introduce a newly-revised RADAR report that it recently created, produced and filed. (Revised RADAR Report (dkt. #325-1).) Millennium contends that it produced this report on the heels of the court's March 6, 2015, opinion and order and rolled it out to customers on March 9th. (Notice Regarding Revised RADAR Report (dkt. #325).) In response to plaintiffs' claim that the revised report is untimely, having been produced after the close of discovery on February 27, 2015, Millennium contends that Rule 26(e) contemplates supplementation of discovery responses up to the time of trial. Millennium's reliance on that section is odd, since it applies to mandatory disclosures of incomplete or incorrect responses, and its previous

²² Plaintiffs also appear to agree that a RADAR Report revised to remove a comparative graph is non-infringing. Regardless, that would almost certainly be a question for the court alone, given its finding that the original RADAR Report infringed as a matter of law, so that if in dispute the issue could be argued to the court after the jury proceeds to deliberate on invalidity.

disclosures were apparently *neither* until after the close of discovery. As a result, Millennium's disclosure obligation was certainly not untimely.

Putting aside this issue, Millennium has nevertheless failed to demonstrate why *this* report (as opposed to the previously disclosed, long-offered reports) is relevant to its reasonable royalty calculation. Millennium appears to concede it is not, contending instead that the March 2015 revised report is relevant to willfulness because it demonstrates that Millennium "ceased using the accused graphed portions of the RADAR Report promptly after this Court rejected Millennium's claim construction." (Def.'s Opp'n (dkt. #334) 9.) The fact that Millennium changed its behavior *after* the court found infringement, however, is not relevant to the jury issue on willful infringement: whether the "objectively-defined risk [of infringement] . . . was either known or so obvious that it should have been known to the accused infringer." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*).

Finally, Millennium contends that the creation of this new report is relevant to the jury's calculation of damages because it creates an end date -- the date on which infringement ceased. On this much, the court agrees. Millennium may submit testimony and evidence establishing that it ceased production of the infringing report on March 9, 2015. Accordingly, plaintiff's motion is denied in part and granted in part. Millennium may submit evidence and introduce argument about the timely-produced, long offered RADAR reports that do not contain the graphed results as evidence of a non-infringing substitute during the damages phase of the trial. Millennium may also produce evidence and testimony that it ceased production of the infringing report on or about March 9,

2015, for purposes of arguing for an end date for any damages calculation. In all other respects, plaintiff's motion is granted.

E. Ninth Motion in Limine: Exclude Evidence that Millennium Customers Can Opt Out of Receiving Graphed Results and Argument that the Number of Infringing Products Is Inflated (dkt. #291)

Plaintiffs seek an order excluding: (1) evidence that Millennium's customers could opt out of receiving a RADAR report without comparative graph results; and (2) any argument by Millennium that the number of infringing products is inflated, on the basis that Millennium could have tracked the number of customers who opted out of receiving the infringing graphed results, but failed to do so. Given its failure to track opt-outs, plaintiffs contend that any uncertainty in the amount of infringing sales must be construed against Millennium. (Pls.' Ninth Mot. (dkt. #291) 2-3 (citing cases).) For the same reasons, plaintiffs further argue that Millennium should not be allowed to introduce evidence that Millennium's customers have the ability to opt out of receiving graphed results, because that would invite the jury to speculate as to the number of non-infringing products sold.

In response, Millennium concedes that it did not track the type of report it sold on an ongoing basis between June 2011 to March 17, 2012, but was able to "derive" the number of RADAR reports issued with graphed results, and from that, was able to estimate the breakdown of graphed versus ungraphed reports over the course of the infringing period. (Def.'s Opp'n (dkt. #335) 2-3.) The court agrees with Millennium that as long as a witness -- likely Diane Hancock, Director of Engineering at the time of

implementation of the accused graphs -- provides an adequate foundation for this analysis, Millennium is free to introduce both evidence that it sells a RADAR report without the graphed results *and* the estimated breakdown of reports with and without the graphed results during the infringing period. Ameritox remains free to challenge the weight the jury should give to this estimation through cross-examination. Plaintiffs are, of course, free to argue that any uncertainty or confusion as to the amount of Millennium's sales of RADAR reports containing the graphed results should be construed against Millennium for failing to keep precise records of such sales. Plaintiffs may also provide the court with legal authority for a jury instruction to the same effect *outside* the context of spoliation, which they have not shown. Accordingly, the court will deny this motion in limine.

F. Tenth Motion in Limine: Exclude Evidence that Other Companies Do or Do Not Offer Graphed Results (dkt. #292)

Plaintiffs seek an order excluding evidence of other companies offering reports that do or do not contain graphed comparative results, but fails to develop any argument in support of this motion. Moreover, as Millennium points out, this evidence is relevant to several damages considerations, including whether the claimed invention was a sales driver in the market, the availability of noninfringing alternatives, and how consumers make purchasing decisions. The court finds no basis for plaintiffs' concern that this evidence will result in mini-trials about whether other parties are infringing, especially since infringement is no longer at issue in this case. Even if such a concern had merit, it is outweighed by the probative value of this evidence. The court also denies plaintiffs'

motion to the extent that they open the door as to secondary considerations of obviousness. (*See* Def.'s Opp'n (dkt. #336) 2.).

G. Eleventh Motion in Limine: Exclude Testimony or Evidence Concerning Ameritox's Investors (dkt. #293)

Plaintiffs seek an order excluding evidence pertaining to Ameritox's investors, in particular Bain Capital. In response, Millennium indicates it has no intent to submit this evidence, but does seek clarification as to two pieces of evidence it intends to submit. First, Millennium intends to introduce testimony and evidence that the former President of U.D. Testing, Robert Bennett, who signed the license agreement between Ameritox and U.D. Testing, obtained a 25% ownership stake in Ameritox subsequent to the execution of that license agreement. Because plaintiffs' damages expert relies on that license agreement, Millennium asserts without explanation that "[t]his evidence bears directly on the comparability (or lack thereof) of the U.D. Testing license to the hypothetical negotiation." (Def.'s Opp'n (dkt. #337) 2.) This argument seems a bit of a stretch, since Millennium offers no evidence that Bennett: (1) planned to obtain an interest in Ameritox at the time he negotiated the license for U.D. Testing; or (2) received his interest for less than full value. Absent such details, Bennett's subsequent acquisition of an ownership interest in Ameritox could just as easily suggest how much he values its technology, as he obtained a deal that was not arms-length. In case the court is missing some nuance to Millennium's argument, the court will reserve on this particular issue pending further argument at the final pretrial conference.

Second, Millennium seeks to introduce a report prepared by Bain & Company as a consultant for Ameritox in 2010, shortly before the date of the hypothetical negotiation. Bain & Company appears to be a separate entity from Bain Capital. *See* “Bain & Company,” Wikipedia (last visited Mar. 26, 2015) (“Bain & Co. is an entirely separate entity from Bain Capital. Bain Capital is a private investment firm specializing in private equity (PE), public equity, leveraged debt asset, venture capital, and absolute return investments. Bain Capital does not provide management consulting services to its clients.”). Regardless, Millennium may introduce this report without needing to make any reference to the fact that Bain Capital is an Ameritox investor.

Accordingly, the court will grant as unopposed Ameritox’s eleventh motion in limine, reserving on the issue of whether Millennium may introduce evidence or testimony that the former President of Testing became an investor in Ameritox after the parties entered into a license agreement.

H. Millennium’s Motion in Limine to Exclude Expert Testimony of Carl D. Degen (dkt. #303)

Millennium asserts two main reasons for the motion: (1) Degen’s testimony is unreliable because he failed to apportion the reasonable royalty to the patented invention, ignoring the entire market rule; and (2) Degen’s testimony on the U.D. Testing License should be excluded because it rests on unreliable underlying information.

Millennium’s motion actually conflates two concerns. The first is that Degen failed to consider the fact that Millennium sells products without the graphed results, but that does not impact the royalty rate analysis. Instead, that information may be relevant

to the jury's overall determination of the royalty base. The second concern is that Degen failed to account properly for that portion of the royalty rate *not* attributable to the patented invention. This dispute is really about whether Degen could rely on the underlying license as a starting point to calculate a reasonable royalty for the patented invention or whether that license is for a broader product. Millennium is certainly free to cross-examine Degen on this issue or otherwise argue that the \$6 royalty rate used in the U.D. Testing product reflects an entire product, and not just the value of the patented invention. In particular, Millennium may challenge the basis for Degen's understanding that the other rights conveyed in the U.D. Testing License were included at no additional cost, or that the upfront \$2 million payment covered those other rights, as well as challenge his ultimate conclusion that \$6 per sample fee is an accurate reflection of the value of the patented technology alone.

Ultimately, however, whether the RADAR reports with graphed results contain other information may not matter since the royalty rate under the U.D. Testing license appears to be for technology comparable to that of the patented invention. While Millennium is free to offer evidence and argue otherwise, that argument goes to weight, not admissibility.

**I. Millennium's Motion in Limine to Exclude Improper Testimony
Regarding the U.D. Testing License (dkt. #276)**

Relatedly, Millennium seeks to exclude testimony from two witnesses, Harry Leider and Todd Gardner, regarding Ameritox's license negotiation and subsequent license agreement with U.D. Testing, Inc., on the basis that neither has personal

knowledge regarding this topic as required by Rule 602.²³ Millennium also seeks to exclude Carl Degen from purporting to rely on conversations with these two individuals in forming his reasonable royalty calculation.

The crux of Millennium's argument is that neither Leider nor Gardner was an Ameritox employee at the time of the negotiation and execution of that licensing agreement in 2005, and more importantly, they both testified during their respective depositions that they lacked knowledge about the licensing agreement because it predated both of them. (Def.'s Br. (dkt. #352) 4-8.) In response, plaintiffs contend that during the course of Dr. Leider's employment with Ameritox, he has developed knowledge about U.D. Testing's technology at the time of the negotiation, in particular its commercial readiness, and it is *that* knowledge Degen is relying upon for purposes of his royalty opinion. At the very least, plaintiffs contend that they should be afforded an opportunity to lay the foundation for Leider's personal knowledge of the U.D. Testing license and Degen's reliance on it. The court agrees. Plaintiffs should make an advance proffer as to Leider's personal knowledge of the commercial readiness of U.D. Testing's technology in and around March 2005, as well as how that knowledge relates to those who actually negotiated the license.

As for Gardner, plaintiffs contend that in his role as Chief Financial Officer and Chief Operating Officer since April 2006, Gardner has personal knowledge of Ameritox's performance under the U.D. Testing license and can also testify about Ameritox's consideration of the licensing agreement in its negotiations with Marshfield on the

²³ Gardner was Ameritox's corporate designee under Rule 30(b)(6) on the topic of any license between Ameritox and U.D. Testing, among other topics.

licensing of the patent-in-suit. The court agrees that this appears to be a proper area of testimony for Gardner and will not exclude it on 602 grounds. Plaintiffs further contend that “Gardner’s high-level position as the Chief Operating Officer has provided him with admissible personal knowledge of the UDT License and terms thereof even though he may have learned this information from another source.” (Pls.’ Opp’n (dkt. #352) 8.) This contention will also require an advance proffer for the court to assess.

Accordingly, the court will reserve on Millennium’s motion to exclude Leider and Gardner’s testimony. Moreover, if Ameritox fails to submit admissible evidence forming the basis of Degen’s opinion testimony on the UD Testing license agreement, the court will entertain a renewed motion by Millennium to strike that testimony as well.

IV. Plaintiffs’ Willful Infringement Claim

A. Motion in Limine to Exclude Evidence of Claimed Willful Infringement (dkt. #278)

Plaintiffs have alleged and intend to pursue at trial a claim that defendants’ infringement was willful, thereby permitting (but not requiring) the court to award enhanced damages. 35 U.S.C. § 284 (“[T]he court may increase the damages up to three times the amount found or assessed.”); *Beatrice Foods Co. v. New Eng. Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991) (“It is well-settled that enhancement of damages must be premised on willful infringement or bad faith.”) (citations omitted). Millennium seeks to exclude any evidence or argument on Ameritox’s willfulness claim on the basis that Ameritox cannot meet the threshold of the objective inquiry for willfulness as a matter of law. Alternatively, Millennium asks the

court to prohibit Ameritox from introducing this evidence until after the jury has deliberated on liability.

To establish willful infringement, Ameritox “must show by clear and convincing evidence” that (1) “the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent,” and (2) “this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer.” *In re Seagate Tech.*, 497 F.3d at 1371. This motion in limine concerns the first prong -- the “objective determination of recklessness” -- which is a question for the court, not the jury. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1006-07 (Fed. Cir. 2012).

“[T]he ‘objective’ prong of *Seagate* tends not to be met where an accused infringer relies on a reasonable defense to a charge of infringement.” *Id.* at 1005-06 (internal citation and quotation marks omitted); *see also Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010) (overturning jury’s finding of willful infringement, finding that defendant raised a “substantial question as to the obviousness” of the patent in suit); *Douglas Dynamics*, 747 F. Supp. 2d at 1112 (granting summary judgment on willful infringement claim where there was “reasonable difference of opinion” and a “close question”).

Millennium contends that plaintiffs cannot meet the objective prong of willful infringement with regard to the ’680 patent because its § 101 defense and alternative claim construction (as well as its related defenses of noninfringement, enablement, and utility) were objectively reasonable. As an initial point, plaintiffs respond that

Millennium's § 101 defense cannot protect it from a willful infringement claim after the Supreme Court's decision in *Alice Corporation v. CLS Bank International*, 134 S. Ct. 2347 (2014), decided three years before the infringement at issue here. While the court cited several recent cases in its discussion of Millennium's § 101 challenge in the court's summary judgment opinion, the core requirement that an invention must supply a "new and useful" result to be patent eligible dates back to the nineteenth century. *See Le Roy v. Tatham*, 55 U.S. 156, 159 (1852). As such, the court rejects plaintiffs' argument that Millennium cannot rely on a § 101 defense to rebut a claim that its position was not objectively reasonable.

While the court agrees with Millennium that it may *consider* whether its § 101 defense was objectively reasonable, the court declines to do so at this time. Instead, the court will hear the evidence presented at the liability phase of the trial -- and perhaps evidence while the jury is deliberating on liability that goes specifically to willful infringement -- before determining whether Millennium's § 101 defense was objectively reasonable.

As for Millennium's argument that its claims construction was also objectively reasonable, the court declines to decide the issue on the eve of trial. As described in the court's opinion granting plaintiffs' summary judgment on infringement of the '680 patent described, Millennium's defense primarily relied on an argument that it does not know the *actual* dosage taken by those individuals making up the comparison population. (3/6/15 Op. & Order (dkt. #256) 3 n.1.) Even if Millennium's argument that the patent claims (rather than the examples in the specification) disclose a comparison population

for a known prescribed dose, Millennium presents no credible basis to hold that the patent also claims known *actual* dosage for the comparison population, much less expressly narrows its claims in that way. (*Id.* at 4.) Moreover, Millennium's utility and enablement defenses -- both of which it is no longer pursuing -- focus on its failed claims construction argument for the "quantifying" step. As described in the court's summary judgment decision, Millennium's claims construction was deeply flawed (2/19/15 Op. & Order (dkt. #215) 24-27), making it difficult for Millennium to overcome Ameritox's evidence that Millennium's construction of step (f) was not objectively reasonable.

In its motion, Millennium also seeks an order prohibiting any evidence of willful infringement until after the jury has determined liability. As described above, the court has already granted that request. *See supra* Section I. As for Millennium's remaining request, the court will reserve on the issue of whether Ameritox has demonstrated through clear and convincing evidence that Millennium acted despite an objectively high likelihood that its actions constituted infringement of a valid patent at least until the close of evidence on the liability phase of trial. To the extent necessary, the court will hear any additional testimony on the objective prong of the willful infringement claim while the jury is deliberating on validity.

B. Motion in Limine to Preclude Certain Expert Testimony of Dr. Paul J. Orsulak (dkt. #283)

Millennium seeks an order excluding plaintiffs' liability expert, Dr. Paul Orsulak, from testifying in the willful infringement part of this trial. Millennium contends that Dr. Orsulak's opinion on willfulness is simply a "regurgitation of the documentary

record,” namely the timeline of Millennium’s awareness of the ‘680 patent and its development of the RADAR report, “culminating in Dr. Orsulak’s one paragraph opinion that it ‘looks like’ Millennium’s launch of the RADAR Report was ‘suspiciously quick.’” (Def.’s Mot. (dkt. #283) 4 (quoting Orsulak Rebuttal Report (dkt. #118) ¶ 213).) Millennium posits three main reasons for excluding this testimony: (1) Dr. Orsulak was not disclosed -- and plaintiffs disavowed his role -- as an expert on willfulness; (2) the testimony falls outside of his areas of expertise; and (3) such testimony would be substantially more prejudicial than probative under Rule 403.

In response, plaintiffs explain that they simply disavowed offering Dr. Orsulak’s opinion on Millennium’s subjective intent or state of mind, but that they reserved the possibility of calling Dr. Orsulak to testify about Millennium’s “awareness and copying of the Rx Guardian CD product, and Millennium’s timeline to launch the infringing service.” (Pls.’ Opp’n (dkt. #340) 1 (emphasis removed).) Plaintiffs further argue that these areas fall within Dr. Orsulak’s area of expertise and are relevant to plaintiffs’ willful infringement claim.

The court agrees with Millennium that the Dr. Orsulak’s recitation of the documentary record is not helpful to the trier of fact, even if it is necessary to involve the jury in a willfulness determination. Expert testimony will not assist the jury in its consideration of the timing of Millennium’s knowledge of the ‘680 patent and its actions in developing the RADAR Report to determine whether the “objectively-defined risk [of infringement]. . . was either known or so obvious that it should have been known to the accused infringer” -- the subjective prong of the willful infringement claim. Accordingly,

the court will grant this motion in limine, but will allow Dr. Orsulak to testify briefly to the court on the objective prong.

V. Millennium's Willful Infringement Defense

A. Plaintiffs' Third Motion in Limine: Exclude Advice of Counsel Defense (dkt. #280)

Plaintiffs contend that Millennium waived its advice of counsel defense through its President Howard Appel's testimony that he had no knowledge that Millennium sought any sort of advice concerning potential infringement. (Pls.' Third Mot. (dkt. #280) 2.) Plaintiffs also request that the court bar any testimony "related to Millennium's belief concerning infringement or the validity of the asserted patent," since that "necessarily implicates advice of counsel" as well. (*Id.*)

In its response, Millennium does not object to the core of plaintiffs' motion, stating that it does not intend to raise an advice of counsel defense. Millennium, however, opposes the second part of Ameritox's motion. The court agrees with Millennium that plaintiffs' attempt to block *all* evidence or testimony concerning Millennium's belief of noninfringement or invalidity of the '608 patent goes too far. Accordingly, the court will grant in part and deny in part this motion in limine. Millennium will not be allowed to present evidence or argue that it relied on the advice of counsel -- a defense it has disavowed -- but Millennium may present evidence and testimony during the second phase of trial with regards to its belief that the '680 patent was invalid and the RADAR report did not infringe that patent. The court will await

further argument from counsel, but it appears that this evidence and testimony goes to the objective prong of the willful infringement claim.

B. Plaintiffs' Seventh Motion in Limine: Exclude Evidence Concerning the Alleged Reasonableness of Millennium's Litigation Defenses, Argument that Plaintiffs Must Prove Copying to Prove Willfulness, and Any Mention of Potential Treble Damages (dkt. #286)

This motion covers three separate areas of evidence and testimony. First, plaintiffs seek to exclude evidence concerning the alleged reasonableness of Millennium's litigation defenses. The court agrees that this evidence should be excluded from the jury because it goes to the objective element of the willful infringement claim, which is a question for the court, not the jury. The court, however, will consider this issue while evidence is presented to the jury on liability. To the extent the parties wish to submit additional evidence solely concerning the objective prong of the willful infringement claim, the court will also hear that evidence while the jury is deliberating on liability. Accordingly, the court will grant this portion of the motion as to introduction of this evidence to the jury, but deny it in all other respects.

Second, plaintiffs seek to exclude any argument that Ameritox "must prove Millennium copied Ameritox's Rx Guardian CD service to prove willful infringement." In support of this motion, plaintiffs contend that the proper inquiry is not whether the defendant copied a competitor's commercial embodiment, but rather whether they knew or should have known that it was infringing a valid patent. As Millennium points out, however, copying an alleged invention *can* form the basis of a willful infringement finding. (Def.'s Opp'n (dkt. #347) 7 (citing *Knorr-Bremse Systeme Fuer Nutzfahrzeuge*

GmbH v. Dana Corp., 383 F.3d 1337, 1348-49 (4th Cir. 2004) (“There are many circumstances that may create an appropriate predicate for a finding of willful infringement, and hence punitive damages, including deliberate copying”)).) If plaintiffs open the door by presenting evidence that Millennium copied the Rx Guardian CD product, then Millennium is of course free to put forth evidence refuting this claim. Ultimately, however, the jury will be instructed on the proper standard for considering the subjective prong of the willful infringement claim, which does not *require* a finding of copying. Accordingly, the court will grant in part and deny in part the second portion of this motion.

Third, plaintiffs seek an order barring Millennium from informing the jury that a willfulness finding comes with a potential trebling of damages, citing Rules 402 and 403. Millennium opposes this portion of the motion, arguing that this information is appropriate, citing pattern jury introductory instructions informing the jury of the possibility of treble damages upon a finding of willful infringement. (Def.’s Opp’n (dkt. #347) 7-8 (quoting Federal Jury Practice & Instructions, 3A Fed. Jury Pract. & Instr. Ch. 158 Instructions (6th ed. 2014) (“The court may, in its discretion, increase the damages up to three times the amount found or assessed. A finding of willful infringement authorizes enhanced damages, but does not mandate an award of increased damages.”))).) Notably, this instruction comes from lengthy pattern introductory instructions, covering a variety of areas of patent law, but is not located in any substantive instructions on willful infringement in this or any other set of pattern instructions reviewed by this court.

The court finds no basis for informing the jury of the possible impact of its decision on the subjective element of the willful infringement claim. The jury's role will be limited to determining whether any objectively-defined risk of infringement (assuming the court finds one) was either known or so obvious that it should have been known to Millennium. Millennium articulates no reason for the jury to be advised of the possible impact of its decision on this issue. The court also agrees with Ameritox that awareness of the possibility of treble damages may prejudice the jury. Accordingly, the court will grant this portion of the motion in limine.

VI. Miscellaneous Motions In Limine

A. Plaintiffs' Fourth Motion in Limine: Exclude Evidence Concerning Prior Litigations Involving Ameritox and Millennium (dkt. #281)

Plaintiffs' seek an order excluding evidence of prior litigation between Ameritox and Millennium, most notably Millennium's false advertising claim against Ameritox filed in November 2010 in the District of Maryland. *Millennium Laboratories, Inc. v. Ameritox, Ltd.*, Civil Action No. 1:10-cv-3327 (D. Md.). Plaintiffs argue that that this evidence is not relevant and, even if relevant, any probative value would be outweighed by the prejudice to Ameritox. There appears to be agreement that any specific reference to that lawsuit has no place in this trial. Millennium contends that certain evidence, admissions or arguments made by Ameritox in that litigation are relevant to its obviousness claim and to plaintiffs' damages and willfulness claims. In particular, Millennium directs the court to evidence submitted by Ameritox during that trial indicating the "overuse or underuse, or other capabilities of comparison, did *not* drive

purchasing decisions.” (Def.’s Opp’n (dkt. #349) 4.) Millennium argues that this evidence would be relevant to rebut a claim of commercial success due to copying. Consistent with the court’s discussion above (*see supra* Section II.E.), the jury will be instructed that in considering whether an invention was *not* obvious, they may consider whether the claimed invention was commercially successful. Should plaintiffs open the door and present evidence of the commercial success of the patented invention as part of their defense to Millennium’s obviousness claim, then Millennium may introduce evidence that Ameritox, its employee(s) and its expert(s) previously disclaimed in a prior litigation that the patented invention drove the sales of its products. Preferably this will be done by impeachment or reading in sworn statements by a party opponent, but the court would also consider some other, more direct statement from the parties. Accordingly, the court directs the parties to attempt to agree on a joint, straightforward statement, or failing that, to submit alternative statements to the court on or before Thursday, April 9th.

In addition, Millennium contends that this same evidence is relevant to the damages phase of the trial. In particular, Millennium argues this evidence bears on *Georgia-Pacific* Factor 8, the commercial success of the patented product. The court agrees. Millennium may introduce evidence of Ameritox’s admissions in a prior lawsuit that the patented invention did not drive sales of its Rx Guardian CD product. The parties are to agree jointly on an appropriate statement on this subject as well, or alternatively submit separately-proposed statements, for the court’s consideration by April 9th.

Finally, Millennium contends that Ameritox took the position in the false advertising case that its Rx Guardian and Rx Guardian CD products “could determine dose compliance,” and that this evidence is relevant to showing Millennium’s “reasonable, good faith belief” that it “was not doing what Ameritox was doing.” (Def.’s Opp’n (dkt. #349) 7.) As an initial matter, the court is concerned that this argument veers too closely to Millennium’s failed claims construction argument. In particular, the court is concerned with Millennium’s continuing efforts to conflate normalized data of patients’ metabolization of a particular drug with individualized data monitoring actual compliance. Even if this argument had merit in the willfulness context, whether Millennium’s belief that the RADAR reports did not infringe the ‘680 patent was reasonable or held in good faith would go to the *objective* prong of the willfulness claim and, therefore, will only be considered by the court outside the jury’s consideration of that claim.

Accordingly, for the reasons described above, the court will grant in part and deny in part Ameritox’s motion.

B. Motion In Limine to Exclude Irrelevant Litigation and Financial Information (dkt. #300)

Finally, Millennium seeks to exclude evidence or testimony regarding “irrelevant” litigation and financial information pursuant to Federal Rules of Evidence 401, 402, and 403. In particular, Millennium seeks to exclude evidence or reference to the (1) unfair competition lawsuit between Millennium and Ameritox in the Middle District of Florida, and in particular the jury verdict (entered against it) and an allegation of spoliation of

evidence, (2) Department of Justice investigations into both parties, and (3) litigation involving former Millennium employees. Plaintiffs also wish to “avoid all of these issues during trial in this case.” As such, the court will grant Millennium’s motion as unopposed.

In opposing the motion, however, plaintiffs also direct the court to two types of evidence they seek to introduce as part of their damages cases. The first apparently was introduced in the Florida litigation and involves net revenue per specimen in March 2005, when Ameritox entered into a licensing agreement with U.D. Technology, compared to June 2011, the date of the hypothetical negotiation in 2011. Plaintiffs would offer this evidence to rebut the testimony of Millennium’s expert Bero that the U.D. Technology license is not comparable because of changing market conditions. Moreover, plaintiffs also seek to admit evidence of Ameritox’s and Millennium’s respective average net revenue per specimen of approximately \$210 in June 2011 in order to demonstrate that the \$6 royalty rate sought by Ameritox is reasonable. The court agrees with Ameritox that this evidence may well be relevant to its damages claim. That ruling takes it outside the court’s grant of Millennium’s motion to exclude “irrelevant” litigation or financial information. To the extent either side is somehow confused about that, hopefully this clarification is sufficient.

Second, plaintiffs seek to introduce evidence demonstrating that Millennium relied on the infringing graphed results to seek refinancing beginning in October 2011, shortly after the date of the hypothetical negotiation, and again as recently as March 2014. The court again agrees with plaintiffs that this evidence is at least arguably

relevant to how Millennium valued or at least purported to value the infringing portion of its RADAR Reports product, and accordingly may counter evidence Millennium seeks to present -- and for which the court has denied plaintiffs' motions in limine -- that the value of the RADAR Reports is in the non-infringing portions. Although this too has nothing to do with Millennium's motion, the court further clarifies that this financial information may also be admissible.

VII. Exhibits

Given that the parties have now submitted exhibit lists totaling 1,334 (plaintiffs: 237; defendant: 1,097), the court is concerned that the parties have (1) not taken sufficient time to actually consider what exhibits will realistically be moved into evidence at this trial, as opposed to used for impeachment or other purposes; (2) failed to consider adequately more practical, effective means to present evidence to a jury, including use of summaries under Fed. Evid. R. 1006; and (3) made little effort to govern their submissions based on likely, meritorious objections by the other side. That concern remains notwithstanding the unsolicited assurances to the contrary by defendant's counsel. (Dkt. #377.) The court is, however, hopeful that as a result of its rulings on the parties' motions in limine as set forth above, many of the proposed exhibits will be withdrawn. The court is also amenable to a designation of exhibits that will not be offered into evidence during the first phase of trial (validity), so that the focus of the pretrial conference can be on a more discrete list of exhibits, with the remainder (going to damages and willfulness) addressed during jury deliberations on validity.

Accordingly, whether by phone or in person, the court directs the parties to meet (again) in good faith no later than 5 p.m. on Monday, April 6, 2015, to confer and pare down their exhibit lists further. The parties shall then submit no later than noon on Tuesday, April 7th, revised exhibit lists reflecting exhibits they may actually seek to have admitted at trial and any remaining objections to those exhibits in a form required by this court.

ORDER

IT IS ORDERED that:

- 1) The parties' joint request for expedited guidance on order of proofs at trial (dkt. #374) is GRANTED. The court will follow its usual practice.
- 2) Plaintiffs Ameritox, Ltd. and Marshfield Clinic, Inc.'s motion to exclude testimony of Alan H. Wu, Ph.D. (dkt. #246) is DENIED.
- 3) Plaintiffs' motion to exclude the expert testimony of Richard F. Bero (dkt. #274) is DENIED.
- 4) The court RESERVES on defendant Millennium Health, LLC's motion in limine to exclude improper testimony regarding the U.D. Testing License (dkt. #276).
- 5) Plaintiffs' motion in limine 1 (dkt. #277) is DENIED.
- 6) Defendant's motion to exclude evidence directed to claimed willful infringement (dkt. #278) is GRANTED IN PART AND DENIED IN PART as set forth above.
- 7) Plaintiffs' motion in limine 2 (dkt. #279) is GRANTED IN PART AND DENIED IN PART as set forth above.
- 8) Plaintiffs' motion in limine 3 (dkt. #280) is GRANTED IN PART AND DENIED IN PART as set forth above.
- 9) Plaintiffs' motion in limine 4 (dkt. #281) is GRANTED IN PART AND DENIED IN PART as set forth above. The parties shall attempt to agree on a joint, short statement on statements made or positions taken by parties in previous litigation, or submit for the court's consideration alternative, proposed statements on or before April 9, 2015.
- 10) Plaintiffs' motion in limine 5 (dkt. #282) is DENIED.

- 11) Defendant's motion in limine to preclude certain expert testimony of Dr. Paul J. Orsulak (dkt. #283) is GRANTED as set forth above.
- 12) Plaintiffs' motion in limine 6 (dkt. #285) is DENIED.
- 13) Plaintiffs' motion in limine 7 (dkt. #286) is GRANTED IN PART AND DENIED IN PART as set forth above.
- 14) Plaintiffs' motion in limine 8 (dkt. #287) is GRANTED IN PART AND DENIED IN PART as set forth above.
- 15) Plaintiffs' motion in limine 9 (dkt. #291) is DENIED.
- 16) Plaintiffs' motion in limine 10 (dkt. #292) is DENIED.
- 17) Plaintiffs' motion in limine 11 (dkt. #293) is GRANTED as unopposed.
- 18) Plaintiffs' motion in limine 12 (dkt. #294) is DENIED;
- 19) Plaintiffs' motion in limine 13 (dkt. #295) is GRANTED.
- 20) Plaintiffs' motion in limine 14 (dkt. #296) is DENIED.
- 21) Defendant's motion in limine to exclude evidence or testimony regarding irrelevant litigation and financial information (dkt. #300) is GRANTED as unopposed.
- 22) Defendant's motion in limine to exclude testimony of Carl G. Degen (dkt. #303) is DENIED.
- 23) Whether by phone or in person, the parties shall meet in good faith no later than 5 p.m. on Monday, April 6, 2015, to confer and pare down their exhibit lists further.
- 24) The parties shall then submit no later than noon on Tuesday, April 7th, revised exhibit lists reflecting exhibits they may actually seek to have admitted at trial and any remaining objections to those exhibits in a form required by this court.

Entered this 3rd day of April, 2015.

BY THE COURT:

/s/

WILLIAM M. CONLEY
District Judge